

Application No. 10/078,816 5 of 14
Reply dated 22 September 2005
Responsive to Examiner's Answer mailed on 1 August 2005

REMARKS

Request for Reopening of Prosecution Under 37 CFR § 41.39(b)(1)

The Examiner's Answer mailed on 1 August 2005 contained a statement that the previously appealed claims were rejected under new grounds of rejection. According to 37 CFR § 41.39(b), the two options available to the appellant in this instance are to reopen prosecution and to maintain the appeal. The option of reopening prosecution is hereby elected. The present paper constitutes the Reply under 37 CFR § 1.111 required when exercising this option.

Amendment to the Claims

Independent Claims 1, 10, and 17 have been amended to recite that the dehydration indicator comprises an alphanumeric character indicative of a level of dehydration. Support for this wording is found throughout the specification and drawings as originally filed, including on page 2 at lines 2-5, on page 6 at lines 17-35, on page 7 at lines 22-23, and in Figures 5, 6, 7, and 8.

Comments on Examiner's Answer

Under *Status of Amendments After Final* in the Examiner's Answer, it was stated that "[t]he amendment after final rejection filed on 22 February 2005 has been entered." It is respectfully noted that no such amendment was filed. Instead, an Advisory Action was mailed from the Office on that date.

Under *Grouping of Claims* in the Examiner's Answer, it was stated that "[t]he rejection of claims 1-20 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7)." It is respectfully noted that this statement is incorrect and inappropriate, for at least the following reasons:

- the entirety of 37 CFR § 1.192 was deleted a year ago. As explicitly recited within brackets in the July 2005 version of the Rules, section 1.192 was "removed and reserved, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004";
- as explicitly recited in slide 17 of the **Final Rules: Practice Before the BPAI** slide set available at <http://www.uspto.gov/web/offices/dcom/bpai/fr2004/moreinfo.html>, the section of the revised Appeal Brief format entitled Grounds of rejection to be reviewed on

Application No. 10/078,816 6 of 14
Reply dated 22 September 2005
Responsive to Examiner's Answer mailed on 1 August 2005

appeal replaced both the "issues for review" and "grouping of claims" sections in the previous format; and

- it is stated on the same slide in the section entitled Argument that "[a]ny claim(s) argued separately should be placed under a subheading", *i.e.*, rather than stating that any claims stand or fall together, appellants are now expected to simply identify claims argued separately by placing them under a subheading in the Argument section.

Thus, the requirements of the revised appeal procedure that became effective in September 2004 were fully met in the Appeal Brief submitted on 13 April 2005.

The ***Grounds of Rejection*** section in the Examiner's Answer contained new rejections under 35 USC § 103 over the previously cited Neading *et al.* reference in view of the newly cited Hsu reference and the previously cited Lee reference. However, no mention was made of the previous rejections under 35 USC § 102 that were the subject of the Appeal. It is respectfully presumed that only the new rejections under 35 USC § 103 are presently in effect and that the previous rejections under 35 USC § 102 were withdrawn and therefore need not be addressed in this Reply. If this presumption is incorrect, an opportunity to reply on the correct basis is hereby requested.

Claim Rejections Under 35 U.S.C. § 103 – Neading *et al.* in view of Hsu

Claims 1, 2, 4 through 12, and 14 through 20 were rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,515,194 to Neading *et al.* in view of U.S. Patent No. 5,922,283 to Hsu.

According to MPEP § 2143:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Application No. 10/078,816 7 of 14
Reply dated 22 September 2005
Responsive to Examiner's Answer mailed on 1 August 2005

Claims 1, 10, and 17

By this standard, a *prima facie* case of obviousness has not been established with respect to the amended independent claims, for at least the following reasons.

In this Reply, independent Claims 1, 10, and 17 have been amended to recite that the dehydration indicator comprises an alphanumeric character indicative of a level of dehydration. As is explained in the subject Application, the alphanumeric character indicative of a level of dehydration is an important component of several of the disclosed embodiments for the reason that the present invention was developed in order to provide a signal that can be interpreted by a caregiver, rather than being a laboratory tool for use by specially trained persons. See, for example, page 1, lines 19-27, and page 4, line 3 through page 5, line 9.

In contrast, neither of the cited references discloses an alphanumeric character as part of any structure alleged in the rejections to be equivalent to the claimed invention. Therefore, the cited references fail to teach or suggest all of the limitations of the independent claims. Also, the cited references contain no suggestion or motivation to modify their teachings to make the present invention.

Additionally, the following points in this section of the Examiner's Answer bear comment, just as they did in the previous responses.

Claims 3 and 13

In the Examiner's Answer, Claims 3 and 13 were again referenced in the context of a qualitative indication of specific gravity. However, Claims 3 and 13 do not mention a qualitative indication, i.e., do not contain such a limitation. Instead, these two claims are directed to a translucent cover. Therefore, the references to a qualitative indication continue to not make sense with respect to these two claims, which do not contain such a limitation. In addition, claims that are numbered 3 and 13 clearly are not encompassed within the listing of "Claims 1, 2, 4-12, and 14-20" at the top of page 4 of the Examiner's Answer, so it is not understood why they were mentioned on page 5 of same.

Application No. 10/078,816

8 of 14

Reply dated 22 September 2005

Responsive to Examiner's Answer mailed on 1 August 2005

Claims 5, 6, 19, and 20

In the Examiner's Answer, **Claims 5, 6, 19, and 20** were again rejected on the basis that the indicator of Neading *et al.* comprises an indicium, the indicium being a color change. However, the definition of an indicium is "a distinctive mark" and the definition of a mark is "a written or printed symbol" (both from Merriam-Webster® Online Dictionary). A color change might indicate something and might be called an "indicator" of something, but **a color change is not a distinctive written or printed symbol and is therefore not an indicium.**

Claims 8 and 14

In the Examiner's Answer, **Claims 8 and 14** were again rejected on the basis that the "indicator 14A, 16 is covered by a semipermeable membrane 14B". However, this characterization of the disclosure of Neading *et al.* continues to be inaccurate, for at least the following reasons.

Element 14A is the *peripheral edge* of the fluid transport layer 14 and element 14B is the *central portion* of the same fluid transport layer 14 (column 2, lines 50-54; Figures 1-6). Thus, **element 14A is not covered by element 14B.**

Element 16 is the *wetness indicator* and is located at the *peripheral edge* 14A of the fluid transport layer 14 (column 2, lines 54-57; column 3, lines 57-60; Figures 1, 3), not in the *central portion* 14B. Specifically, the *central portion* 14B is "spaced inwardly from the *peripheral edge* 14A" (column 3, lines 33-35, italics added; Figures 1, 3, 5, 6, 7). Thus, **element 16 is likewise not covered by element 14B.**

Instead, the *wetness indicator* 16 of Neading *et al.* is exposed, i.e., not covered by any other layer, and is therefore visible at the *peripheral edge* 14A (column 2, lines 4 and 56; column 3, line 62; column 4, lines 45, 49, and 67; column 5, line 23; column 6, lines 6, 17, 23, and 29; Figures 1, 3). **In fact, this exposure and visibility of the indicator along the peripheral edge is a key feature of the invention.**

Application No. 10/078,816 9 of 14
Reply dated 22 September 2005
Responsive to Examiner's Answer mailed on 1 August 2005

In the Advisory Action mailed on 22 February 2005, it was erroneously stated that "figures 7 and 8 of Neading show the indicator not extending beyond, and therefore covered by, the topsheet of the article". Since there is no Figure 8 in the reference, it is presumed that it was intended to refer to Figure 6 and 7. However, this characterization contradicts the explicit description of the embodiments shown in these figures. With regard to Figure 6, it is recited in column 4, lines 51-59 that "the peripheral edge 14A of the fluid transport layer 14 containing the wetness indicator 16 is exposed along at least one or both of opposite side portions 12E, 12F of the diaper substrate 12". As for Figure 7, it is recited in column 4, line 60 through column 5, line 4 that "[t]he wetness indicator 16 is provided on and exposed...along a portion of the peripheral edge 12A of the diaper substrate 12". Thus, the inventors in Neading *et al.* did not contradict themselves, as would be required for the rejection to have any basis in fact, but instead confirmed in these two paragraphs that **their wetness indicator 16 is exposed in all of their embodiments**, instead of being covered as alleged. In fact, applying the same erroneous interpretation of the figures without reference to the corresponding portions of the text would lead to the same erroneous conclusion with respect to every figure except Figure 3, but such a result would clearly be incorrect, thus belying the erroneousness of this interpretation of the figures.

Thus, the fundamental structural characteristic of the dehydration indicator of the present invention being covered by another structural element is not present in the allegedly equivalent structure of the Neading *et al.* reference. This fact, alone, is sufficient to negate the rejections.

In addition, as has previously been pointed out, the cited reference does not disclose a **semipermeable membrane** as that term is used in the subject Application and in the pertinent field of art. The allegation that the fibrous layers 14 and 18 of the Neading *et al.* reference, which do not cover the wetness indicator 16, as explained again above, fall within the broadest reasonable interpretation of the claim term is without basis in fact, for at least the following reasons.

Several representative examples of the definition and usage of the term "semipermeable membrane" have been provided in previous papers. These references were, without exception, confirmatory of the propriety of its usage in the subject Application. In addition, Perry's

Application No. 10/078,816 10 of 14
Reply dated 22 September 2005
Responsive to Examiner's Answer mailed on 1 August 2005

Chemical Engineer's Handbook, Sixth Edition, McGraw-Hill Inc., 1984, recites in its section entitled **Membrane Processes** on page 17-14 that:

A membrane is a thin barrier separating two fluids. The barrier prevents hydrodynamic flow so that transport through the membrane is by sorption and diffusion. The property of the membrane describing the rate of transport is its permeability. A membrane is semipermeable if, under identical conditions, it transports different molecular species at different rates.

The same section goes on to list polymeric membrane materials including, for example, the cellulose acetate material listed in the subject Application, and to describe the uses of these membranes in dialysis and reverse osmosis processes. Thus, there is no factual question as to whether or not the term "semipermeable membrane" is known and used in the pertinent field of art or whether or not the accepted meaning includes the layers 14 and 18 of the Neading *et al.* reference as alleged in the rejections; it does not.

Furthermore, the present inventors clearly intended to distinguish semipermeable membranes from other types of selectively permeable layers. As explicitly recited on page 8 at lines 23 through 28:

In certain embodiments, the top layer may alternatively comprise a selectively permeable layer 75, a dissolving layer, a pH sensitive layer, or a coating. Exemplary selectively permeable layers may include meshes, tissues, micro or macroporous films, semipermeable membranes, and other selectively permeable materials as known in the art. Suitable exemplary semipermeable membranes include cellulose acetate, cellulose diacetate, cellulose triacetate, agar acetate, beta glucan acetate, polymeric epoxides, semipermeable polyurethanes, and semipermeable polyglycolic acid.

As is evident from the above portion of the disclosure, the present inventors explicitly contrasted semipermeable membranes and other selectively permeable materials, and specifically distinguished meshes and tissues from semipermeable membranes. The layers 14 and 18 of the Neading *et al.* reference, which do not cover the wetness indicator 16, as explained again

Application No. 10/078,816 11 of 14
Reply dated 22 September 2005
Responsive to Examiner's Answer mailed on 1 August 2005

above, might fall within the same category as meshes or tissues, but clearly do not fall within the scope of the meaning of "semipermeable membrane" that is known and used in the field of chemical engineering. Additionally, it is well-known that chemical engineering is the technical field from which the developers of diapers and other disposable absorbent articles are commonly drawn.

Furthermore, the justification in the Examiner's Answer of the rejections on the basis that the "instant specification...does not assign special meaning...to the limitation 'semipermeable membrane'" is improper. According to MPEP 2111, "[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach" (underlining added for emphasis). This point is further explained in MPEP 2111.01.II, where it is stated that "[c]laim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art" (underlining added for emphasis). Thus, it is not necessary for the present inventors, who are working in their field of art, to "assign special meaning" to a term that is well-known and commonly used in that same field of art.

Therefore, the allegation that the fibrous layers 14 and 18 of the Neading *et al.* reference fall within the broadest reasonable interpretation of the claim term "semipermeable membrane" is contrary to fact.

Summary regarding rejections over Neading *et al.* and Hsu

The cited prior art references, either singly or in combination, fail to teach or suggest all of the limitations of the rejected claims. The references similarly fail to provide any suggestion or motivation to modify or combine their teachings to make the present invention.

Therefore, the requirements of MPEP 2143 for the establishment of a *prima facie* case of obviousness have not been met with respect to any of the independent claims or any of the remaining rejected claims, which depend from and thereby contain all of the limitations of the independent claims. Accordingly, it is respectfully requested that the rejections of Claims 1, 2, 4 through 12, and 14 through 20 under 35 USC § 103(a) over the Neading *et al.* and Hsu references be reconsidered and withdrawn.

Application No. 10/078,816 12 of 14
Reply dated 22 September 2005
Responsive to Examiner's Answer mailed on 1 August 2005

Claim Rejections Under 35 U.S.C. § 103 – Neading *et al.* in view of Hsu and Lee

Claims 3 and 13 were rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,515,194 to Neading *et al.* in view of U.S. Patent No. 5,922,283 to Hsu and further in view of U.S. Patent No. 5,947,943 to Lee.

Claims 3 and 13 were rejected on the basis that the Neading *et al.* reference, in combination with the Hsu reference, discloses all aspects of the claimed invention but remains silent with respect to the outer cover, that Lee discloses a translucent outer cover, and that it would have been obvious to make the outer cover of Neading *et al.* translucent as taught by Lee, “so that the indicator may be easily viewed without removing the article”. In addition, it was stated that “[t]he outer cover 16 provides a barrier to moisture...which prevents liquids from leaking from the article and protects the indicator from exterior liquids”. It was also stated that “the translucent outer cover of Lee would provide the additional advantage of protecting the otherwise exposed indicator of Neading, while still allowing the indicator to be visible from the outside”.

Claims 3 and 13 depend from and thereby contain all of the limitations of the independent **Claims 1 and 10**, respectively. As discussed above, **Claims 1 and 10** have been amended to recite that the dehydration indicator comprises an alphanumeric character indicative of a level of dehydration. Neither of the cited references discloses an alphanumeric character as part of any structure alleged in the rejections to be equivalent to the claimed invention. Therefore, the cited references fail to teach or suggest all of the limitations of the rejected claims. Also, the cited references contain no suggestion or motivation to modify their teachings to make the present invention.

In addition, the disclosure of the Neading *et al.* reference contains no indication that the exposure of the wetness indicator is problematic; instead, this exposure is repeatedly explicitly emphasized as advantageous. Specifically, there is no mention in this reference of any problem with regard to preventing liquids from leaking from the article or of any need to “protect” the indicator.

Application No. 10/078,816 13 of 14
Reply dated 22 September 2005
Responsive to Examiner's Answer mailed on 1 August 2005

The Hsu reference and the Lee reference likewise mention nothing regarding such a problem. Instead, in the Lee reference, it is essential that the moisture barrier layer 28 of the backsheet 16 be translucent because the wetness-indicating material 24 is disposed beneath and entirely covered by the layer 28 and would otherwise not be visible. As is explicitly recited at column 3, lines 53-55, "the moisture barrier 28 is transparent or translucent, so that the visual appearance of the wetness-indicating material 24 can be perceived through the moisture barrier 28." In other words, in the structure disclosed in the Lee reference, the "visual indicator" that is the object of the invention would not be visible if the outermost layer of the backsheet were not translucent. Thus, the only suggestion or motivation provided by the Lee reference relative to a translucent layer is that a layer that covers a "visual indicator" must be translucent so that the indicator beneath it can be seen. This fact is extremely basic; objects hidden behind other opaque objects cannot be seen. However, as previously explained, the indicator of the Neading *et al.* reference is already visible and it is not covered. Therefore, the teaching of Lee to make a covering layer translucent is not relevant to the article of Neading *et al.*, in which the indicator is exposed rather than being covered.

Thus, the basis for the rejection appears to be merely an allegation that a translucent cover layer could be added to the article of Neading *et al.* However, as clearly stated in MPEP 2143.01, the mere fact that references could have been combined or modified, or that the level of skill in the art may have been adequate to combine or modify them, is insufficient to establish a prima facie case of obviousness. In addition, given the utter lack of expression in the Neading *et al.* reference of a need to cover the indicator or in the Lee reference of any purpose for a translucent cover other than to make an underlying layer visible, the statement that it would have been obvious to do so is clearly based on nothing more than either conjecture or the application of impermissible hindsight in light of the disclosure of the present invention. The mere fact that a modification can be made is not a sufficient basis to justify an obviousness rejection.

Furthermore, the Neading *et al.* reference explicitly teaches away from reapplying the structure taught by Lee, to wit:

In the Lee patent, a wetness-indicating material is disposed on an interior-facing side of a back sheet of a diaper. The Lee wetness-indicating material changes its

Application No. 10/078,816 14 of 14
Reply dated 22 September 2005
Responsive to Examiner's Answer mailed on 1 August 2005

appearance after it is exposed to water. The Lee patent, however, appears to be unduly complex and costly for achieving this objective" (column 1, lines 45-46).

Thus, the proposed modification to the structure taught by Neading *et al.* is unnecessary. Furthermore, modifying the structure in precisely the way that Neading *et al.* explicitly considered and rejected can hardly be considered an improvement.

Summary regarding rejections over Neading *et al.*, Hsu, and Lee

The cited prior art references, either singly or in combination, fail to teach or suggest all of the limitations of the rejected claims. The references similarly fail to provide any suggestion or motivation to modify or combine their teachings to make the present invention; in fact, the Neading *et al.* reference explicitly teaches away from using the teachings of the Lee reference.

Therefore, the requirements of MPEP 2143 for the establishment of a *prima facie* case of obviousness have not been met with respect to the rejected claims. Accordingly, it is respectfully requested that the rejections of Claims 3 and 13 under 35 USC § 103(a) over the Neading *et al.*, Hsu, and Lee references be reconsidered and withdrawn.

Summary of this Response

The independent claims have been amended to add a structural distinction relative to the cited references. The rejections of the claims have been argued. In light of this amendment and these remarks, it is respectfully requested that the rejections be reconsidered and withdrawn and that the pending claims be allowed.

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